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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,084	07/14/2003	Donald Jeffery Zack	001107.00370	3952

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EXAMINER	
WANG, CHANG YU	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,084	ZACK ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 01, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a method of inhibiting neuronal cell death comprising administering an antibody in a subject, classified in for example class 424, subclass 130.1.

II. Claims10-19, drawn to a method of preventing neuronal cell death comprising administering a nucleic acid molecule or a protein in a mammal, classified in for example class 514, subclass 44 or class 514, subclass 2.

III. Claims 20-28, drawn to a method of identifying regions of neuronal cell death in a patient comprising administering an antibody, classified in for example class 424, subclass 130.1.

IV. Claims 29, 34, and 35, drawn to a method of screening for neuronal cell death in a patient comprising detecting a body fluid with an antibody or a nucleic acid, classified in for example class 435, subclass 7.1 or class 435, subclass 6.

V. Claims 30-33, drawn to a method of promoting neuronal cell death in a patient comprising administering a neuronal marker protein or a nucleic acid molecule, classified in for example class 514, subclass 2 or class 514, subclass 44.

VI. Claims 36-53, drawn to a method to identify candidate drugs for treating neuronal cell death, classified in class 435, subclass 7.21.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II III, IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this instant case, first, the procedures, materials, and equipments used in these different methods are very different from each other. For example, the agents or materials used for the method of promoting neuronal cell death (Group V) are totally different from those in inhibiting or preventing neuronal cell death (Groups I-II). The biological effects of the agents for promoting neuronal cell death are prone to induce apoptosis whereas those for inhibiting neuronal cell death are prone to enhance trophic effects. Second, the patient populations in a method of diagnosing a disease (Groups III and IV) are very distinct from in those for treating a disease (Groups I-II, and V). The mental status, behavior, symptoms and the medication conditions as well as the etiology and pathology are very different between these two categories. Third, the functions and effects are different among these different groups. Since the patient populations are different, the patients' conditions and expecting effects and outcomes are also very different. Further, the materials, procedures and outcomes involved in a method of identifying regions of neuronal cell death in a patient (Group III), which are *in vivo* procedures and involved in different equipments for diagnoses, are very different

from a method of screening using a body fluid (Group IV), which are *in vitro*. Moreover, the steps, materials, and results for the method of identifying a candidate drug for treating neuronal cell death (Group VII) are very distinct from those in inhibiting, preventing or screening neuronal cell death (Groups I-V). For example, the method of identifying a candidate drug for treating neuronal cell death can be performed *in vitro*. However, the method of preventing neuronal cell death in a patient is involved in administering a molecule *in vivo*, and may be involved in imaging diagnostic equipments, which may not be applied for identifying a candidate drug. Thus, the inventions I, II, III, IV, V and VI are patentably distinct.

3. Furthermore, in addition to the election of one of the above VI groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:

A. A single designated embodiment of molecules as stated in Groups I-VI selected from: the molecules recited in claims 1, 10, 11, 20, 29, 30, 32, 34, 35, 36, 39, 42, 45, 48 and 51 if one of the Groups I-VI is elected.

B. A single designated type of molecule as stated in Groups II, IV and V selected from: A) antibody, B) protein or C) nucleic acid if one of the Groups II, IV or V is elected.

C. A single designated molecule as detected in the Group VI selected from: A) RNA or B) protein if Group VI is elected.

D. A single designated effect of a test compound as stated in the Group VI selected from: A) decreases or B) increases activity if Group Vi is elected

4. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products and processes, restriction is deemed to be proper because the products indicated as groups A-D constitute patentably distinct inventions for the following reasons. Each of the molecules has a unique structural feature and function, which requires a unique search of the prior art. In addition, each of the polypeptides, antibodies and polyucleotides has a distinct structural feature, which also requires a separate search of the prior art in different classifications. The inventions indicated as Group A-C differ in structure and function as they are composed of divergent amino acids, antibodies and polynucleotides, and also the use for each molecule are different, which they are differentially able to bind or mediate bological functions. Further, the molecular mechanisms underlying the effects of increased activity are very different from those in decreased activity (Group D). There are total different sets of molecules involved in each specific activity in signal transduction and downstream target genes. Since the mechanisms involved in these different activities are different, the strategies for treatment and the outcomes of the treatment are inherently different. Therefore, groups

A-D constitute very divergent subject matters. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-VI and a single molecular embodiment and activity from groups A-D to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither Groups I-VI nor groups A-D are species election requirements; rather each of the Groups I-VI and groups A-D are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups. It is noted that while one of the groups A-D may not be applicable to one of the Groups I-VI, applicant must elect one of each in order to be fully compliant.

Species Election

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

i. Species of disorder as stated in Groups I-III are as follows:

A) Retinal cell degeneration, B) Alzheimer's disease, C) Diabetic retinopathy, D) Huntungton's disease, E) Spinal cord injury, F) Parkinson's disease, G) Glaucoma, or H) age-related macular degeneration.

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. The claims are deemed to correspond to the species listed above in the following manner:

If one of the Groups I-III is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for the disorder from Group i for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 10, 11, 20, 29, 30, 32, 34, 35, 36, 39, 42, 45, 48, 51 are generic.

12. The species listed above are patentably distinct for the following reasons:

13. These species are distinct because they are different disorders. The causes and molecular mechanisms involved in each of the neurodegenerative diseases or neurological disorders are very distinct. Each specific species differs with respect to its etiology and potential molecular mechanisms contributed to its pathological condition. In addition, the patient populations in each pathological condition are different. It requires different diagnoses and medications. Therefore, each species is patentably distinct.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-VI, a single molecular embodiment and effect from groups A-D, and a single species for disorder from group i to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected group and species.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

17. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should

applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
October 17, 2005

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER